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09/704,235	11/01/2000	Raghbir S. Bhullar	RDID 0030 US	2645

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EXAMINER
NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
1743	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/704,235	BHULLAR ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 November 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2,3,5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "12" has been used to designate both a flat cover (in Figure 1) and a concave cover (in Figure 2). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Double Patenting

2. Claims 13 and 16 are objected to under 37 CFR 1.75 as being a substantial duplicates of claims 2 and 4, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The only difference between Claim 13 and Claim 2 and between Claim 16 and 4 is that Claims 13 and 16 specifically require that the opening in the cover be between the top and bottom sides of the cover, but is this not a necessary structural feature of an opening through a cover (opening: "an open space affording passage or view", first definition under "opening" in Webster's II New Riverside University Dictionary, 1988)?

Claim Rejections - 35 USC § 112

3. Claims 7, 20, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 7 recites the limitation "the cover includes a second opening" in line 1. There is insufficient antecedent basis for this limitation in the claim (there is no first opening in the cover in Claim 1);

b) Claim 20 recites the limitation "the reagent" in line 9. There is insufficient antecedent basis for this limitation in the claim; and

c) Claim 20: -- capillary -- should be inserted before "channel" to be consistent with the preamble.

Note that dependent claims will have the deficiencies of base and intervening claims.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-3, 9, 10, and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Charlton et al. (US 5,759,364).

Addressing Claim 1, Charlton et al. teach a biosensor comprising

a substrate (element 36 in Figure 1);

a reagent positioned on the substrate (element 44 in Figure 1); and

a cover (element 46 in Figure 1) including a top side and a generally flat bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the reaction region (inherent from concave portion, 48, of the cover).

Addressing Claims 2 and 3, for the channel extending as claimed note opening 50 in relation to the channel in Figure 1.

Addressing Claim 9, for electrodes as claimed note electrodes 39 and 40 in Figure 1.

Addressing Claim 10, as seen in Figure 1 opening 50 is spaced apart from electrodes 39 and 40.

Addressing Claim 12, adhesive as claimed is disclosed in col. 3, ll. 16-35, especially ll. 29-35.

Addressing Claim 13, Charlton et al. teach a biosensor comprising

a substrate (element 36 in Figure 1);

a reagent positioned on the substrate (element 44 in Figure 1); and

a cover (element 46 in Figure 1) including a top side and a generally flat bottom side, and an opening (element 50 in Figure 1) extending between the top and bottom sides, the bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the reaction region (inherent from concave portion, 48, of the cover).

Addressing Claim 14, a U-shaped interior as claimed may be disconnected from Figure 1.

Addressing Claim 15, for electrodes as claimed not electrodes 39 and 40 in Figure 1.

6. Claims 1-9, 12, 13, and 16-19 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hodges et al. (US 6,174,420 B1).

Addressing Claim1, Hodges et al. teach a biosensor comprising

a substrate (bottom element 13 in Figure 15);

a reagent positioned on the substrate (col. 4, ll. 56-65); and

a cover (top element 13 in Figure 15) including a top side and a generally flat bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the reaction region (Figures 12 and 15).

Addressing Claims 2-5 and 16, for a channel extending as claimed note openings 16 in relation to the channel in Figure 12.

Addressing Claim 6, the openings (elements 16 in Figure 12) are disrupted concave surfaces since they do not each have a smooth curvature, but instead have sharply joined edges.

Addressing Claim 7, two openings 16 may be seen in Figure 12.

Addressing Claims 8 and 19, as seen in Figure 12 the channel expands and then converges from the first opening toward the second opening.

Addressing Claim 9, for electrodes as claimed consider electrodes 13 in Figure 15.

Addressing Claim 12, for adhesive as claimed note layers 3 in Figure 15 and col. 4, ll. 26-37.

Addressing Claim13, Hodges et al. teach a biosensor comprising

a substrate (bottom element 13 in Figure 15);

a reagent positioned on the substrate (col. 4, ll. 56-65); and

a cover (top element 13 in Figure 15) including a top side and a generally flat bottom side, and an opening (openings 16 in Figure 12) extending between the top and bottom sides, the bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the reaction region (Figures 12 and 15).

Addressing Claim 17, for edges intersecting the openings as claimed see Figure 12.

Addressing Claim 18, for notches as claimed note openings 16, which include notches, in Figure 12.

7. Claims 1-3, 9, 10, and 12-15 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Uenoyama et al. (US 6,125,292).

Addressing Claim 1, Uenoyama et al. teach a biosensor comprising

a substrate (element 4 in Figure 1C);

a reagent positioned on the substrate (col. 4, ll. 59-65); and

a cover (element 5 in Figure 1C) including a top side and a generally flat bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the reaction region (element 1 in Figure 1C).

Addressing Claims 2 and 3, for a channel extending as claimed note opening 8 in relation to the channel in Figure 1C.

Addressing Claim 9, for electrodes as claimed note electrodes 2 and 3 in Figure 1C.

Addressing Claim 10, as seen in Figure 1C opening 8 is spaced apart from electrodes 2 and 3.

Addressing Claim 12, adhesive as claimed may be found in col. 4, ll. 54-59.

Addressing Claim 13, Uenoyama et al. teach a biosensor comprising

a substrate (element 4 in Figure 1C);

a reagent positioned on the substrate (col. 4, ll. 59-65); and

a cover (element 5 in Figure 1C) including a top side and a generally flat bottom side, and an opening (opening 8 in Figure 1C) extending between the top and bottom sides, being coupled

to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the reaction region (element 1 in Figure 1C).

Addressing Claim 14, a U-shaped interior as claimed may be discerned form Figure 1A.

Addressing Claim 15, for electrodes as claimed note electrodes 2 and 3 in Figure 1C.

8. Claims 1-3, 9, and 13-15 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Ikeda et al. (EP 0964059 A2).

Addressing Claim 1, Ikeda et al. teach a biosensor comprising

a substrate (element 1 in Figure 1);

a reagent positioned on the substrate (col. 4, ll. 27-31); and

a cover (element 4 in Figure 1) including a top side and a generally flat bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the reaction region (col. 4, ll. 32-42 and Figure 1).

Addressing Claims 2 and 3, for a channel extending as claimed note opening 8 in relation to the channel in Figure 1.

Addressing Claim 9, for electrodes as claimed note electrodes 2 and 5 in Figure 1.

Addressing Claim 13, Ikeda et al. teach a biosensor comprising

a substrate (element 1 in Figure 1);

a reagent positioned on the substrate (col. 4, ll. 27-31); and

a cover (element 4 in Figure 1) including a top side and a generally flat bottom side, and an opening (opening 8 in Figure 1) extending between the top and bottom sides, being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the reaction region (col. 4, ll. 32-42 and Figure 1).

Addressing Claim 14, a U-shaped interior as claimed may be discerned from Figure 1.

Addressing Claim 15, for electrodes as claimed note electrodes 2 and 5 in Figure 1.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar et al. (US 6,6319,719 B1).

Addressing Claim 1, Bhullar et al. teach a biosensor comprising

a substrate (element 12 in Figures 1 and 2);

a reaction area (element 20 in Figures 1 and 2); and

a cover (element 14 in Figure 1) including a top side and a generally flat bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the reaction region.

Bhullar et al. do not directly mention an embodiment that has reagent in the reaction region; however, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have reagent in the reaction area because Bhullar et al. disclose that "[a]

suitable dry reagent can be situated in the reaction region." See col. 2, ll. 58-59; col. 5, ll. 11-29; and Claim 9. As taught by Bhullar et al., with a reagent analytes of interest, such as blood sugar, can be detected. See col. 5, ll. 11-13.

Addressing Claim 9, electrodes as claimed are implied by Claim 11 and col. 5, ll. 37-39, which discloses having electrochemical detecting apparatus in the reaction region.

Addressing Claim 10, as seen in Figures 1 and 2 the openings 21 are above the reaction region where the electrodes would be located.

Addressing Claim 11, Bhullar et al. do not mention the height to the channel being less than 10 microns, although a height of 100 microns or less is taught (col. 2, ll. 27-30). Barring evidence to the contrary, such as unexpected results, having the channel height less than 10 μm is a design choice. In particular, it is the biosensor taught by Bhullar et al. scaled down in size to better accommodate a smaller sample volume.

13. Claims 2, 3, 7, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar et al. (US 6,6319,719 B1) as applied to Claims 1 and 9-11 above, and further in view of Uenoyama et al. (US 6,125,292) and Bhullar (EP 1098000 A2).

Addressing Claims 2 and 3, although Bhullar et al. teach having the channel extend between an opening adjacent the cover and the reagent (note vent 21 in Figures 1 and 2), Bhullar et al. do not disclose having the opening in the cover. However, having an opening in the cover,

such as a vent in the cover of a biosensor, was known at the time of the invention as shown, for example, by Figure 1C (note element 8) of Uenoyama et al. and Figure 14 of Bhullar EP 1098000 A2 (note element 52). Barring evidence to the contrary, such as unexpected results, the location of the vent is a design choice, with the primary concern being avoiding sample fluid leaking through the vent.

Addressing Claim 7, it should first be noted that the Examiner has assumed that this claim was meant to depend from Claim 2 because Claim 2 provides antecedent basis for a second opening in the cover. Two openings are disclosed in Figure 2 of Bhullar et al. As argued in the rejection of Claim 2, above, having vents in the cover instead of the walls of a biosensor was a known design variant at eh time of invention.

Addressing Claim 13, Bhullar et al. teach a biosensor comprising

a substrate (element 12 in Figures 1 and 2);

a reaction area (element 20 in Figures 1 and 2); and

a cover (element 14 in Figure 1) including a top side and a generally flat bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the reaction region.

Bhullar et al. do not directly mention an embodiment that has reagent in the reaction region; however, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have reagent in the reaction area because Bhullar et al. disclose that "[a] suitable dry reagent can be situated in the reaction region." See col. 2, ll. 58-59; col. 5, ll. 11-29;

and Claim 9. As taught by Bhullar et al., with a reagent analytes of interest, such as blood sugar, can be detected. See col. 5, ll. 11-13.

Also, although Bhullar et al. teach having the channel extend between an opening adjacent the cover and the reagent (note vent 21 in Figures 1 and 2), Bhullar et al. do not disclose having the opening between the top and bottom sides of the cover. However, having an opening through the cover, such as a vent in the cover of a biosensor, was known at the time of the invention as shown, for example, by Figure 1C (note element 8) of Uenoyama et al. and Figure 14 of Bhullar EP 1098000 A2 (note element 52). Barring evidence to the contrary, such as unexpected results, the location of the vent is a design choice, with the primary concern being avoiding sample fluid leaking through the vent.

14. Claims 1-3 and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar (EP 1098000 A2).

Addressing Claim 1, Bhullar (EP 1098000 A2) teach a biosensor comprising

a substrate (improperly labeled as element 28 in Figure 12; according to col. 6, ll. 21-23 "28" refers to the electrode set);

a cover (element 32 in Figure 12) including a top side and a generally flat bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the sensing region (col. 4, ll. 21-26 and Figure 12).

Bhullar (EP 1098000 A2) does not directly mention an a reagent in the reaction region; however, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have reagent in the reaction area because Bhullar (EP 1098000 A2) discloses "reagent is optional, and may be used to provide electrochemical probes for specific analytes" See col. 8, ll. 39-47. As taught by Bhullar et al., with a reagent analytes of interest, such as blood glucose, can be detected. See col. 8, ll. 47-56.

Addressing Claims 2 and 3, for a channel extending as claimed note opening 52 in relation to the channel in Figure 14 of Bhullar (EP 1098000 A2).

Addressing Claim 9, electrodes as claimed are shown in Figure 12 of Bhullar (EP 1098000 A2).

Addressing Claim 10, as seen in Figure 14 of Bhullar (EP 1098000 A2) opening 52 is spaced apart from electrodes 44.

Addressing Claim 11, Bhullar (EP 1098000 A2) does not mention the height to the channel, although a height in microns is implied because they teach that the channel is a capillary channel (col. 6, ll. 44-46). Barring evidence to the contrary, such as unexpected results, having the channel height less than 10 μm is a design choice. In particular, it is the biosensor taught by Bhullar (EP 1098000 A2) scaled down in size to better accommodate a smaller sample volume.

Addressing Claim 12, using an adhesive is taught in col. 6, ll. 27-29.

Addressing Claim 13, Bhullar (EP 1098000 A2) teach a biosensor comprising

a substrate (improperly labeled as element 28 in Figure 12; according to col. 6, ll. 21-23 "28" refers to the electrode set);

a cover (element 32 in Figure 12) including a top side and a generally flat bottom side, and an opening (opening 52 in Figure 14 of Bhullar (EP 1098000 A2)) extending between the top and bottom sides, being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the sensing region (col. 4, ll. 21-26 and Figure 12).

Bhullar (EP 1098000 A2) does not directly mention an a reagent in the reaction region; however, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have reagent in the reaction area because Bhullar (EP 1098000 A2) discloses "reagent is optional, and may be used to provide electrochemical probes for specific analytes" See col. 8, ll. 39-47. As taught by Bhullar et al., with a reagent analytes of interest, such as blood glucose, can be detected. See col. 8, ll. 47-56.

15. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al. (US 5,759,364).

Charlton et al. teach a biosensor comprising

a substrate (element 36 in Figure 1);

a reagent positioned on the substrate (element 44 in Figure 1); and

a cover (element 46 in Figure 1) including a top side and a generally flat bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the reaction region (inherent from concave portion, 48, of the cover).

Charlton et al. do not mention the height of the channel although it appears to be less than 10 μm because they state "[t]he typical thickness of the entire structure is 6 μm (col. 3, ll. 3-4). In any event, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have the channel height less than 10 μm because the surrounding elements are 10 μm or less in thickness (col. 3, ll. 10-15) and the channel is a capillary channel (col. 3, ll. 23-26) that can accommodate as little as 7μl of sample (col. 9, ll. 61-63).

16. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges et al. (US 6,174,420 B1). Hodges et al. teach a biosensor comprising

a substrate (bottom element 13 in Figure 15);

a reagent positioned on the substrate (col. 4, ll. 56-65); and

a cover (top element 13 in Figure 15) including a top side and a generally flat bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the reaction region (Figures 12 and 15).

Hodges et al. do not mention the height to the channel, although a height in microns is implied because they teach that the channel is a capillary channel (col. 4, ll. 38-44) and that the electrodes, which form the top and bottom surfaces of the channel, are preferably less than 200 microns apart (col. 1, ll. 64-67) . Barring evidence to the contrary, such as unexpected results, having the channel height less than 10 μm is a design choice. In particular, it is the biosensor taught by Hodges et al. scaled down in size to better accommodate a smaller sample volume.

17. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uenoyama et al. (US 6,125,292).

Uenoyama et al. teach a biosensor comprising

a substrate (element 4 in Figure 1C);

a reagent positioned on the substrate (col. 4, ll. 59-65); and

a cover (element 5 in Figure 1C) including a top side and a generally flat bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the reaction region (element 1 in Figure 1C).

Uenoyama et al. do not mention the height to the channel, although a height in microns is implied because they teach that the channel is a capillary channel (col. 5, ll. 48-55) and that a cap, which is used to seal the exposed end of the sensor, is 200 microns in height (col. 7, ll. 20-22). Barring evidence to the contrary, such as unexpected results, having the channel height less

than 10 μm is a design choice. In particular, it is the biosensor taught by Uenoyama et al. scaled down in size to better accommodate a smaller sample volume.

18. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ikeda et al. (EP 0964059 A2).

Ikeda et al. teach a biosensor comprising

a substrate (element 1 in Figure 1);

a reagent positioned on the substrate (col. 4, ll. 27-31); and

a cover (element 4 in Figure 1) including a top side and a generally flat bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the reaction region (col. 4, ll. 32-42 and Figure 1).

Ikeda et al. do not mention the height to the channel, although a height in microns is implied because they teach that the channel is a capillary channel (col. 5, ll. 54-58). Barring evidence to the contrary, such as unexpected results, having the channel height less than 10 μm is a design choice. In particular, it is the biosensor taught by Ikeda et al. scaled down in size to better accommodate a smaller sample volume.

19. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ikeda et al. (EP 0964059 A2) in view of Uenoyama et al. (US 6,125,292) in view of Charlton et al. (US 5,759,364).

Ikeda et al. teach a biosensor comprising

a substrate (element 1 in Figure 1);

a reagent positioned on the substrate (col. 4, ll. 27-31); and

a cover (element 4 in Figure 1) including a top side and a generally flat bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the reaction region (col. 4, ll. 32-42 and Figure 1).

Ikeda et al. do not mention using adhesive between the cover and substrate, although laminating the cover and substrate is taught (col. 4, ll. 32-34), which presumably means pressing and heating.

Laminating or using adhesive to attach the cover and substrate of a biosensor were known alternatives at the time of the invention, as shown be col. 4, ll. 56-59 in Uenoyama et al. and col. 3, ll. 16-36 in Charlton et al. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use adhesive between the cover and substrate as taught by Uenoyama et al. and Charlton et al. in the invention of Ikeda et al. because as taught by Charlton et al., depending on the composition of the materials used a more leakproof capillary space may result when adhesive is used (col. 3, ll. 32-35). Also, it would have been obvious to one with ordinary skill in the art at the time the invention was made to use adhesive if it would be cheaper than lamination and still provide an adequate result.

20. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar et al. (US 6,6319,719 B1) in view of Uenoyama et al. (US 6,125,292) in view of Charlton et al. (US 5,759,364).

Bhullar et al. teach a biosensor comprising

a substrate (element 12 in Figures 1 and 2);

a reaction area (element 20 in Figures 1 and 2); and

a cover (element 14 in Figure 1) including a top side and a generally flat bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the reaction region.

Bhullar et al. do not directly mention an embodiment that has reagent in the reaction region; however, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have reagent in the reaction area because Bhullar et al. disclose that "[a] suitable dry reagent can be situated in the reaction region." See col. 2, ll. 58-59; col. 5, ll. 11-29; and Claim 9. As taught by Bhullar et al., with a reagent analytes of interest, such as blood sugar, can be detected. See col. 5, ll. 11-13.

Bhullar et al. also do not directly mention using adhesive between the cover and substrate, although using an adhesive appears to be implied by col. 5, ll. 7-10, which teaches using a solvent to fix the cover and substrate.

In any event, using adhesive to attaché the cover and substrate of a biosensor was a known alternative at the time of the invention, as shown be col. 4, ll. 56-59 in Uenoyama et al. and col. 3, ll. 16-36 in Charlton et al. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use adhesive between the cover hand substrate as

taught by Uenoyama et al. and Charlton et al. in the invention of Bhullar et al. because as taught by Charlton et al., depending on the composition of the materials used a more leakproof capillary space may result when adhesive is used (col. 3, ll. 32-35). Also, it would have been obvious to one with ordinary skill in the art at the time the invention was made to use adhesive if it would be cheaper than other commonly used techniques, such as heat bonding or mechanical coupling, and still provide an adequate result.

21. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al. (US 5,759,364) in view of Dunn et al. (US 6,326,160 B1) and Petrie ("Handbook of Adhesives and Sealants," McGraw-Hill, 2000, pp. 279-284).

Addressing Claim 20, Charlton et al. teach a method of forming a biosensor having a capillary channel, the method comprising the steps of

providing a substrate (element 36 in Figure 1 and col. 2, ll. 49-52);

providing a cover having a top surface and a bottom surface (element 46 in Figure 1 and col. 3, ll. 13-15); and

attaching the cover to the substrate to form a sealed portion and an unsealed portion that define a channel extending across the reagent (Figure 1; note concave element 48 of the cover, which forms the top of the capillary channel, and reagent 44).

Charlton et al. do not mention attaching the cover to the substrate with adhesive to form a sealed portion as claimed. Charlton et al. laminate or heat press the cover to the substrate. See

col. 3, ll. 13-32. However, Charlton et al. do disclose that adhesive may alternatively be used instead of lamination. See col. 3, ll. 29-35.

Dunn et al. also teach that adhesive may be used alternatively to lamination to form a biosensor. In particular, Dunn et al. teach that thermoset adhesive is a common adhesive that may be used. See col. 10, ll. 36-44. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use thermoset adhesive as taught by Dunn et al. in the invention of Charlton et al. because as taught by Petrie thermoset adhesive is a commonly used structural adhesive that has good heat and solvent resistances. See Table 8.1 on page 282 and the first full paragraph on page 284.

Addressing Claim 21, note electrodes 39 and 40 in Figure 1.

22. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges et al. (US 6,174,420 B1) in view of Dunn et al. (US 6,326,160 B1) and Petrie ("Handbook of Adhesives and Sealants," McGraw-Hill, 2000, pp. 279-284).

Addressing Claim 20, Hodges et al. teach a method of forming a biosensor having a capillary channel, the method comprising the steps of

providing a substrate (bottom element 13 in Figure 15 and col. 3, ll. 49-56);

providing a cover having a top surface and a bottom surface (top element 13 in Figure 15 and col. 4, ll. 26-30); and

attaching the cover to the substrate to form a sealed portion and an unsealed portion that define a channel extending across the reagent (Figures 12 and 15; note capillary channel 11; for reagent see col. 4, ll. 56-65).

Hodges et al. teach attaching the cover to the substrate with adhesive to form a sealed portion as claimed, but do not mention whether the adhesive is a thermoset adhesive. See layers 3 in Figure 15 and col. 4, ll. 26-37.

Dunn et al. also teach that adhesive may be used to form a biosensor. In particular, Dunn et al. teach that thermoset adhesive is a common adhesive that may be used. See col. 10, ll. 36-44. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use thermoset adhesive as taught by Dunn et al. in the invention of Hodges et al. because as taught by Petrie thermoset adhesive is a commonly used structural adhesive and that has good heat and solvent resistances. See Table 8.1 on page 282 and the first full paragraph on page 284.

Addressing Claim 21, note electrodes 39 and 40 in Figure 1.

23. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uenoyama et al. (US 6,125,292) in view of Dunn et al. (US 6,326,160 B1) and Petrie ("Handbook of Adhesives and Sealants," McGraw-Hill, 2000, pp. 279-284).

Addressing Claim 20, Uenoyama et al. et al. teach a method of forming a biosensor having a capillary channel, the method comprising the steps of

providing a substrate (element 4 in Figure 1C);

providing a cover having a top surface and a bottom surface (element 5 in Figure 1C); and

attaching the cover to the substrate to form a sealed portion and an unsealed portion that define a channel extending across the reagent (note capillary channel 1 in Figure 1C; for reagent see col. 4, ll. 59-65).

Uenoyama et al. et al. teach attaching the cover to the substrate with adhesive to form a sealed portion as claimed, but do not mention whether the adhesive is a thermoset adhesive. See col. 4, ll. 54-59.

Dunn et al. also teach that adhesive may be used to form a biosensor. In particular, Dunn et al. teach that thermoset adhesive is a common adhesive that may be used. See col. 10, ll. 36-44. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use thermoset adhesive as taught by Dunn et al. in the invention of Uenoyama et al. because as taught by Petrie thermoset adhesive is a commonly used structural adhesive and that has good heat and solvent resistances. See Table 8.1 on page 282 and the first full paragraph on page 284.

Addressing Claim 21, note electrodes 2 and 3 in Figure 1C.

24. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikeda et al. (EP 0964059 A2) in view of Uenoyama et al. (US 6,125,292), Charlton et al. (US 5,759,364), Dunn et al. (US 6,326,160 B1), and Petrie ("Handbook of Adhesives and Sealants," McGraw-Hill, 2000, pp. 279-284).

Addressing Claim 20, Ikeda et al. teach a method of forming a biosensor having a capillary channel, the method comprising the steps of

providing a substrate (element 1 in Figure 1);

providing a cover having a top surface and a bottom surface (element 4 in Figure 1);

attaching the cover to the substrate to form a sealed portion and an unsealed portion that define a channel extending across the reagent (col. 4, ll. 32-42 and Figure 1).

Ikeda et al. do not mention using adhesive between the cover and substrate, although laminating the cover and substrate is taught (col. 4, ll. 32-34), which presumably means pressing and heating.

Laminating or using adhesive to attaché the cover and substrate of a biosensor were known alternatives at the time of the invention, as shown be col. 4, ll. 56-59 in Uenoyama et al. and col. 3, ll. 16-36 in Charlton et al. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use adhesive between the cover hand substrate as taught by Uenoyama et al. and Charlton et al. in the invention of Ikeda et al. because as taught by Charlton et al., depending on the composition of the materials used a more leakproof capillary space may result when adhesive is used (col. 3, ll. 32-35). Also, it would have been obvious to one with ordinary skill in the art at the time the invention was made to use adhesive if it would be cheaper than lamination and still provide an adequate result.

Ikeda et al. as modified by Charlton et al. and Uenoyama et al. do not disclose using a thermoset adhesive. Dunn et al. also teach that adhesive may be used to form a biosensor. In particular, Dunn et al. teach that thermoset adhesive is a common adhesive that may be used. See col. 10, ll. 36-44. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use thermoset adhesive as taught by Dunn et al. in the invention of Ikeda et al. as modified by Charlton et al. and Uenoyama et al. because as taught by Petrie thermoset adhesive is a commonly used structural adhesive and that has good heat and solvent resistances. See Table 8.1 on page 282 and the first full paragraph on page 284.

Addressing Claim 21, note electrodes 2 and 5 in Figure 1.

25. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ikeda et al. (EP 0964059 A2) in view of Uenoyama et al. (US 6,125,292) in view of Charlton et al. (US 5,759,364).

Ikeda et al. teach a biosensor comprising

a substrate (element 1 in Figure 1);

a reagent positioned on the substrate (col. 4, ll. 27-31); and

a cover (element 4 in Figure 1) including a top side and a generally flat bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the reaction region (col. 4, ll. 32-42 and Figure 1).

Ikeda et al. do not mention using adhesive between the cover and substrate, although laminating the cover and substrate is taught (col. 4, ll. 32-34), which presumably means pressing and heating.

Laminating or using adhesive to attaché the cover and substrate of a biosensor were known alternatives at the time of the invention, as shown be col. 4, ll. 56-59 in Uenoyama et al. and col. 3, ll. 16-36 in Charlton et al. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use adhesive between the cover hand substrate as taught by Uenoyama et al. and Charlton et al. in the invention of Ikeda et al. because as taught by Charlton et al., depending on the composition of the materials used a more leakproof capillary space may result when adhesive is used (col. 3, ll. 32-35). Also, it would have been obvious to one with ordinary skill in the art at the time the invention was made to use adhesive if it would be cheaper than lamination and still provide an adequate result.

26. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar (EP 1098000 A2) in view of Dunn et al. (US 6,326,160 B1) and Petrie ("Handbook of Adhesives and Sealants," McGraw-Hill, 2000, pp. 279-284).

Addressing Claim 20, Bhullar (EP 1098000 A2) teach a method of forming a biosensor having a capillary channel, the method comprising the steps of

providing a substrate (improperly labeled as element 28 in Figure 12; according to col. 6, ll. 21-23 "28" refers to the electrode set);

providing a cover having a top surface and a bottom surface (element 32 in Figure 12 and col. 4, ll. 21-26); and

attaching the cover to the substrate to form a sealed portion and an unsealed portion that define a channel extending across the reagent (note cover 32 and capillary channel 38 in Figure 12 and col. 4, ll. 21-26).

Bhullar (EP 1098000 A2) disclose attaching the cover to the substrate with adhesive in col. 6, ll. 27-29.

Dunn et al. also teach that adhesive may be used to form a biosensor. In particular, Dunn et al. teach that thermoset adhesive is a common adhesive that may be used. See col. 10, ll. 36-44. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use thermoset adhesive as taught by Dunn et al. in the invention of Bhullar (EP 1098000 A2) because as taught by Petrie thermoset adhesive is a commonly used structural adhesive that has good heat and solvent resistances. See Table 8.1 on page 282 and the first full paragraph on page 284.

Addressing Claim 21, note electrodes 28 in Figure 12 (arrow for "28" should point to electrodes; see col. 6, ll. 21-23).

27. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar et al. (US 6,6319,719) in view of Uenoyama et al. (US 6,125,292), Charlton et al. (US 5,759,364), Dunn et al. (US 6,326,160 B1), and Petrie ("Handbook of Adhesives and Sealants," McGraw-Hill, 2000, pp. 279-284).

Addressing Claim 20, Bhullar et al. (US 6,6319,719) teach a method of forming a biosensor having a capillary channel, the method comprising the steps of

providing a substrate (element 12 in Figures 1 and 2);

providing a cover having a top surface and a bottom surface (element 14 in Figure 1);

attaching the cover to the substrate to form a sealed portion and an unsealed portion that define a channel (Figure 1).

Bhullar et al. (US 6,6319,719) do not directly mention an embodiment that has reagent in the reaction region; however, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have reagent in the reaction area because Bhullar et al. disclose that "[a] suitable dry reagent can be situated in the reaction region." See col. 2, ll. 58-59; col. 5, ll. 11-29; and Claim 9. As taught by Bhullar et al. (US 6,6319,719), with a reagent analytes of interest, such as blood sugar, can be detected. See col. 5, ll. 11-13.

Bhullar et al. (US 6,6319,719) also do not directly mention using adhesive between the cover and substrate, although using an adhesive appears to be implied by col. 5, ll. 7-10, which teaches using a solvent to fix the cover and substrate.

In any event, using adhesive to attach the cover and substrate of a biosensor was a known alternative at the time of the invention, as shown be col. 4, ll. 56-59 in Uenoyama et al. and col. 3, ll. 16-36 in Charlton et al. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use adhesive between the cover hand substrate as taught by Uenoyama et al. and Charlton et al. in the invention of Bhullar et al. (US 6,6319,719) because as taught by Charlton et al., depending on the composition of the materials used a more leakproof capillary space may result when adhesive is used (col. 3, ll. 32-35). Also, it would have been obvious to one with ordinary skill in the art at the time the invention was made to use adhesive if

it would be cheaper than other commonly used techniques, such as heat bonding or mechanical coupling, and still provide an adequate result.

Bhullar et al. (US 6,6319,719) as modified by Charlton et al. and Uenoyama et al. do not disclose using a thermoset adhesive. Dunn et al. also teach that adhesive may be used to form a biosensor. In particular, Dunn et al. teach that thermoset adhesive is a common adhesive that may be used. See col. 10, ll. 36-44. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use thermoset adhesive as taught by Dunn et al. in the invention of Bhullar et al. (US 6,6319,719) as modified by Charlton et al. and Uenoyama et al. because as taught by Petrie thermoset adhesive is a commonly used structural adhesive and that has good heat and solvent resistances. See Table 8.1 on page 282 and the first full paragraph on page 284.

Addressing Claim 21, placing electrodes is implied by Claim 11 and col. 5, ll. 37-39, which discloses having electrochemical detecting apparatus in the reaction region.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JILL WARDEN can be reached on (703) 308-4037. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-7719 for regular communications and (703) 305-5433 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguerola
September 3, 2002